

IN THE CLAIMS:

1. (canceled)

2. (canceled).

3. (canceled).

4. (canceled).

5. (canceled).

6. (canceled).

7. (canceled).

8. (cancelled).

9. (cancelled).

10. (cancelled) .

11. (canceled) .

12. (canceled).

13. (canceled).

14. (canceled).

15. (canceled).

16. (canceled) .

17. (canceled).

18. (canceled).

19. (canceled).

20. (canceled).

21. (previously presented) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a

soft tissue layer between the bone structure and an outer skin layer

intended to be in contact with a support structure, comprising:

a protective device to be applied to the body part to be protected; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; and said protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume to reduce the pressure exerted at the interface between the bone structure and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and the support structure; and wherein there is included between the outer skin layer and the inner surface of the protective device at least one of the following:

- a- a layer of dressing;
- b- a layer of medicated dressing;
- c- a layer of hydrocolloid dressing;
- d- a layer of hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- e- a layer of hydrogel;
- f- a layer of hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

- g- a thin film dressing;
- h- a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- i- a layer of gauze dressing;
- j- a layer of gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- k- a layer of non woven-dressing;
- l- a layer of non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- m- a layer of foam dressing;
- n- a layer of foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- o- a layer of material adapted to absorb any excess moisture and drainage;
- p- a layer of material which exhibits moisture vapor permeability for removal of excess moisture; and
- q- a layer of material which exhibits permeability to air for enabling air circulation for removing excess heat and moisture; and

- r- a layer of material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance.

22. (previously presented) A prosthesis for protecting a part of a human body from developing a pressure ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a protective device to be applied to the body part to be protected; said protective device having an inner surface conforming to the body part to which it is applied and having an outer surface suitable for making contact with the support structure; and said protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume to reduce the pressure exerted at the interface between the bone structure and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin layer and between the corresponding outer skin layer and the support structure; and wherein the protective device includes at least one of the following:

- (a) a dressing;
- (b) a medicated dressing;
- (c) a hydrocolloid dressing;

(d) a hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

(e) a hydrogel;

(f) a hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

(g) a thin film dressing;

(h) a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

(i) a gauze dressing;

(j) a gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

(k) a non woven-dressing;

(l) a non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

(m) a foam dressing;

(n) a foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;

- (o) a material adapted to absorb any excess moisture and drainage;
- (p) a material which exhibits moisture vapor permeability for removal of excess moisture; and
- (q) a material which exhibits permeability to air for enabling air circulation; and
- (r) a material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance.

23. (canceled).

24. (canceled) .

25. (canceled).

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29. (canceled.

30. (canceled).

31. (canceled)

32. (canceled).

33. (canceled).

34. (canceled) .

35. (canceled)

36. (canceled).

37. (cancelled).

38. (canceled) .

39. (canceled).

40. (canceled) .

41. (withdrawn) A method for protecting selected body parts from developing pressure ulcers or for healing an existing pressure ulcer comprising the steps of:

ascertaining the body parts of an individual prone to the development of pressure ulcers when the individual is placed on a support surface; and as to each body part ascertained to be prone to the development of a pressure ulcer applying to each different part a protective device having an inner surface conforming to the body part and having an outer surface suitable for making contact with the support surface for enabling the weight associated with each one of said body parts to be distributed over an extended area and volume.

42. (withdrawn) The method as claimed in claim 41, wherein the step of ascertaining the body parts prone to the development of pressure ulcers includes the step of ascertaining at least one of the following: the height, weight, skeletal dimensions of the individual, dimension of body part, weight of body part, contour of body part and shape of the body of the individual and the age, gender level of continence, nutritional status, presence of diseases and state of mind of the individual.

43. (withdrawn) The method as claimed in claim 42 wherein body parts of concern include a bony prominence with a soft tissue layer between the bony prominence and the outer skin and wherein the step of ascertaining whether a body part is prone to developing a pressure ulcer includes ascertaining at least

one of the following: the thickness of the soft tissue, its behavior in compression, its behavior in shear, its behavior in tension, its behavior in friction, and the moisture level of the outer skin layer.

44. (withdrawn) The method as claimed in claim 41 further including the step of placing the individual on a support surface; and wherein the step of applying a protective device to each different part protects the different body parts regardless of the nature of the support surface.

45. (withdrawn) The method as claimed in claim 44 wherein the step of applying a protective device includes attaching a protective device to a selected body part, each protective device placed between the support surface and the body part to be protected, each protective device having an inner surface conforming to the body part to which it is attached and having an outer surface suitable for making contact with the support surface; each protective device having sufficient thickness and softness to distribute the weight of the body part over an extended area and volume such that the pressure exerted between the bony portion associated with the body part and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and the support surface is less than a critical value of pressure (P_c) that would cause a pressure ulcer to develop in that part of the body.

46. (withdrawn) The method as claimed in claim 41, wherein applying a protective device to each different body part includes ascertaining the thickness

of the soft tissue layer of a selected body part and placing a pad between a selected body part and the support surface such that the pressure developed across the soft tissue layer of the corresponding body part is below a certain level.

47. (withdrawn) The method as claimed in claim 46, wherein a portion of the protective device is formed to have one of the following shapes: rectangular, cylindrical, semi-cylindrical, toroidal, ellipsoid, oblong, triangular and a combination thereof.

48. (withdrawn) The method as claimed in claim 47, wherein said pad is for distributing the weight of the body part over an extended area and volume and for reducing the pressure at the interface between the bony portion and its corresponding soft tissue layer, across the corresponding soft tissue layer and at the interface between the corresponding soft tissue layer and the corresponding outer skin and between the corresponding outer skin and a support structure is less than the pressure that would cause a pressure ulcer to develop in that part of the body.

49. (withdrawn) The method as claimed in claim 41 wherein the step of ascertaining various characteristics of an individual to be outfitted with protective devices includes the step of performing at least one of the following: invasively measuring the thickness of the soft tissue layers, non-invasively measuring the thickness of the soft tissue layers, and wherein the step of applying a protective device includes the step of selecting the prosthesis best suited for the person's

body part in order to heal an existing pressure ulcer or to prevent the development of one.

50. (withdrawn) The method as claimed in claim 41 wherein the step of ascertaining the thickness of the soft tissue layer includes measuring the thickness of the soft tissue layer using at least one of the following: X-rays, CAT scans, MRIs, ultrasound, any suitable diagnostic tool.

51. (withdrawn) A kit of protective devices for protecting a selected number of different body parts of a person from developing a pressure ulcer or for healing an existing pressure ulcer, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part, the kit comprising:

a set of different protective devices to be applied to respective body parts to be protected, each protective device having an inner surface conforming to the body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer.

52. (withdrawn) The kit of protective devices as claimed in claim 51 including a series of different sized protective devices for the same body part in order to fit persons of different sizes.
53. (withdrawn) The kit of protective devices as claimed in claim 51 including a protective device for at least one of the following body parts: heel, trochanter, ankle, knee, sacrum, coccyx, ischium, scapula, elbow, buttocks and occiput.
54. (withdrawn) The kit of protective devices as claimed in claim 51 including a series of pads of predetermined thickness which can be attached to the outer surface of selected protective devices for increasing the thickness of the protective device applied to a body part.
55. (withdrawn) The kit as claimed in claim 51 wherein the protective devices include a series of protective devices for a particular body part where the thickness of each prosthesis is different to enable the selection of a more optimum protective device for the needs of a particular person.
56. (withdrawn) The kit as claimed in claim 51 including a series of protective devices for the same body part having different degrees of softness for enabling the selection of a more optimum protective device to meet the needs of a particular person.
57. (withdrawn) The kit as claimed in claim 51 further including wound dressing to provide pressure relief and wound care within the same protective unit.

58. (withdrawn) The kit as claimed in claim 51 further including means for shaping selected protective devices for enabling more precise fitting of the device to the body of a person where better contact is required.
59. (withdrawn) The kit as claimed in claim 51 further including means for adding layers to the inner surface of selected protective devices for protecting the outer skin of the person fitted with a protective device.
60. (withdrawn) The kit as claimed in claim 51, wherein each protective device includes at least one of the following:
- a. a dressing;
 - b. a medicated dressing
 - c. a hydrocolloid dressing;
 - d. a hydrocolloid dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
 - e. a hydrogel;
 - f. a hydrogel dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
 - g. a thin film dressing;
 - h. a thin film dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
 - i. a gauze dressing;

- j. a gauze dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- k. a non woven-dressing;
- l. a non woven-dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- m. a foam dressing;
- n. a foam dressing containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance;
- o. a material adapted to absorb any excess moisture and drainage;
- p. a material which exhibits moisture vapor permeability; and
- q. a material which exhibits permeability to air for enabling air circulation;
- r. a material containing medication including at least one of an antibacterial, anti-inflammatory, anti-fungal, and anti-pain substance; and
- s. material including therapeutic components such as growth factors and wound healing accelerators.

61. (withdrawn) A garment adapted to protect a selected number of different body parts of a person, where each body part to be protected includes a

bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part, the garment comprising a selected number of sections corresponding to said selected number of body parts to be protected; each one of said sections for securing a protective device at a location corresponding to the location of the body part to be protected; and each protective device having an inner surface conforming to the body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer.

62. (withdrawn) The item of attire as claimed in claim 61, wherein the protective devices are secured to the body of the person regardless of movement of the person.

63. (withdrawn) The item of attire as claimed in claim 62, wherein the sections of the item of attire includes flaps for enabling the selective insertion and removal of protective devices.

64. (withdrawn) The item of attire as claimed in claim 61 for securing selected protective devices to selected body parts regardless of the orientation of

the body of the person and for providing protection to the selected body parts regardless of the characteristics of the support surface.

65. (withdrawn) A system for protecting a selected number of different body parts of a person, where each body part to be protected includes a bony portion with a soft tissue layer between the bony portion and an outer skin layer, and where the body part is to be protected when the body part is in contact with a support surface and the weight of the body and the body part causes pressure to be developed at the interface between the bony portion and its corresponding soft tissue layer, across the soft tissue layer and between the skin layer and the support surface which may cause a pressure ulcer to develop in the body part;

means for applying a protective device to selected ones of the body parts to be protected; each such protective device having an inner surface conforming to the body part to which it is to be applied and having an outer surface suitable for making contact with the support surface; each protective device for distributing the weight of its corresponding body part over an extended area for reducing the pressure at the interface between its corresponding bony portion and its corresponding soft tissue layer; and a garment to be placed over at least one body part, said garment having sections located at sites corresponding to the locations of the body part to be protected and said garment adapted to be placed over, at least, a portion of the body of the person for securing at least one protective device to the body part to be protected.

66. (withdrawn) The system as claimed in claim 65 for securing selected protective devices to selected body parts regardless of the orientation of the body

of the person and for providing protection to the selected body parts regardless of the characteristics of the support surface.

67. (canceled).

68. (canceled).

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70. (canceled) .

71. (canceled) .

72. (canceled).

73. (canceled).

74. (canceled) .

75. (canceled) .

76. (canceled) .

77. (canceled) .

78. (cancelled)

79. (canceled) .

80. (canceled) .

81. (canceled) .

82. (canceled) .

83. (withdrawn) A protective device for protecting a part of a human body from developing an ulcer or for healing an existing pressure ulcer, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure, comprising:

a relatively firm mold to be applied to the body part to be protected; said relatively firm mold having an inner surface conforming generally to the body part to which it is applied and having an outer surface suitable for making contact with the support structure;

applying an expandable material between the outer skin of the body part to be protected and the inner surface of its corresponding relatively firm mold, said expandable material expanding as a function of the absorption of fluid as a function of time.

84. (withdrawn) The protective device as claimed in claim 83, wherein the expandable material may include at least one of the following:

- (a) gel formers including at least one of calcium alginate, gelatin and cross-linked polyethylene oxide;
- (b) gum formers including at least one of carboxymethylcellulose, methylcellulose and guar gum;
- (c) compressed fibrous absorbents, such as cardboard; and
- (d) compressed foam materials such as hydrophilic polyurethane foam.

85. (withdrawn) A method for protecting a part of a human body, where the body part includes a bone structure and a soft tissue layer between the bone structure and an outer skin layer intended to be in contact with a support structure such that there is pressure at the interface between the bone structure and the soft tissue layer, across the soft tissue and outer skin layers and at the interface between the outer skin layer and the support structure, the method comprising the step of:



applying an expandable material to the outer skin of the body part to be protected, said expandable material expanding as a function of the absorption of fluid as a function of time.

86. (withdrawn) The method as claimed in claim 85 wherein the body part to be protected is at least one of the heel, trochanter, knee, sacrum, coccyx, ischium, scapula, elbow, ankle, buttocks and occiput; and wherein the expandable material may includes at least one of the following:

- (a) gel formers including at least one of calcium alginate, gelatin and cross-linked polyethylene oxide;
- (b) gum formers including at least one of carboxymethylcellulose, methylcellulose and guar gum;
- (c) compressed fibrous absorbents, such as cardboard; and
- (d) compressed foam materials such as hydrophilic polyurethane foam.

87. (canceled) .

88. (canceled).

89. (canceled).

90. (canceled)